U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

D1237B

Telephone [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Benjamin Cohen, President
The Health Connection, Ltd.
105 Ralph Avenue
Copiague, New York 11726

March 5, 1997

Ref: 42-NYK-97

Dear Mr. Cohen:

This letter is written in reference to your firm's marketing and distribution of SPV-30 Capsules, an herbal extract of the boxwood evergreen tree, which is offered as an antiretroviral for the treatment of HIV/AIDS infections.

SPV-30 is a drug [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)] based on claims for specific disease conditions made in its labeling including published articles, study reports, news releases, and advertising bulletins about SPV-30 that you provide to your customers. It is a "new drug" [§ 201(p)] since SPV-30 is not generally recognized as safe and effective and, therefore, may not be marketed without an approved New Drug Application (NDA) [§505]

The drug is misbranded [§502(a)] because its labeling is false and misleading since it suggests that SPV-30 is safe and effective for its intended use even though this is not the case. The drug is also misbranded [§ 502(f)(1)] because its labeling fails to bear adequate directions for use.

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market and distribute. It is your responsibility to ensure that all of your products are in compliance with the requirements of the Act and its implementing regulations.

For your information, in 1994, the Dietary Supplements Health and Education Act (DSHEA) was enacted. This Act, among its provisions, defined dietary supplements and dietary ingredients, established a new framework for assuring safety; outlined guidelines for literature displayed where supplements are sold; and provided for the use of certain types of claims and nutritional support statements. These claims and statements, however, may not be made about the use of a product to diagnose, prevent, mitigate, treat, or cure a specific disease. Products making disease claims are considered drugs, not dietary supplements.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter as to the specific actions you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232.

Sincerely,

Diana Amador

Diana Amador
Acting District Director

cc [redacted]

cc: HFR-NE1
cc: HFR-NE100
cc: HFR-NE140/QA file
cc: HFR-NE150
cc: HFR-NE150/Comstat Coordinator
cc: HFR-NE1500/Otto Vitillo
cc: HFD-300/HFD-314/Edward Miracco, CSO
cc: HFA-224
cc: HFC-210/CFN 2437319
cc: HFI-35/purged copy
cc: EF (The Health Connection, Ltd.)
cc: warning letter file (42-NYK-97)
cc: circ /chrono.
cc: BAG